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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,365	08/28/2003	Guangwen Wei	#792-A-PCT-US	7677

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Albert Wai-Kit Chan
Law Offices of Albert Wai-Kit Chan, LLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, NY 11357

EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/650,365	WEI ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-16,23-25, 27 and 28* is/are pending in the application.

4a) Of the above claim(s) *12-16,25,27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 August 2003 and 20 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/17/03, 6/9/05 &.* 6/17/2005
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

DETAILED ACTION

1. Applicant's election with traverse of Group I, drawn to recombinant "super-compound" interferon and compositions comprising said "super-compound" interferon in response of 5/20/2005 is acknowledged. Applicants traverse on the basis that the search required to examine, the remaining claim sets extensively overlaps with the search required for Invention 1. Applicants' arguments have been fully considered but are not considered to be persuasive because search for super compound interferon will not automatically yield the method of making such (Invention 2). In addition, Inventions 3 and 4 are drawn to methods of treating or preventing tumors or viral diseases and a search directed to a super-compound interferon will not automatically lead to the identification of the treatment methods using the protein. Therefore, the searches for each of the groups are not coextensive and would be a burden on the Office to search all of the different claims of the groups. The requirement is still deemed proper and is therefore made FINAL. Claims 12-16, 25 and 27-28 are withdrawn as drawn to unelected invention. Thus, claims 1-9, 11 and 23-24 are examined.

Specification

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the

sequence rules (37 CFR 1.821 - 1.825). Applicant is required to provide a paper copy of the CRF in response to the Office Action. **Specifically, the sequences disclosed in Figures 1 and 2 are not accompanied by the required reference to the relevant sequence identifiers. Additionally, the specification discloses sequences at pages 14-17 and 20-21 that are not accompanied by the required reference to the relevant sequence identifiers.**

Drawings

3. Applicants submission of drawings on 8/23/2003 and 1/20/2004 is acknowledged.

Information Disclosure Statement

4. The information disclosure statements filed 11/17/2003, 6/9/2005 and 6/17/2005 have been placed in the application file, but the information referred to therein has not been considered.

Priority

5. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in CHINA on 2/28/2001. It is noted, however, that applicant has not filed a translated copy of the Application No, 01104367.9. Therefore the priority is set forth as the filing date of the instant invention.

Claim Objections

6. Claim 11 is objected to because of the following informalities: It depends on an unelected claim (claim 10). Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11 and 23-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7a. Claims 1, 4-9, 11 and 23-24 are rejected as vague and indefinite because it is unclear what is a "super-compound interferon or "functional equivalent thereof". Applicants on page: 7 lines 13-15 describes that super-compound interferon possesses anti-viral or anti-tumor activity and therefore useful in preventing and treating viral diseases, tumors or cancers. It is well known in the art that Interferon is known to have divers activities such as antiviral, antiproliferative and immunomodulatory activities. Thus it is unclear what is the uniqueness associated with the instant "super-compound interferon". It is also unclear to what polypeptide or protein is this compound functional equivalent of. What physical or functional characteristics will make an interferon a "super-compound interferon"? In addition, Applicants have not provided a SEQ ID to identify this particular polypeptide.

7b. Claim 1 is also rejected as vague and indefinite for reciting the term "changed spatial configuration and improved efficacy" is not defined in the specification. Therefore the metes and bounds of these claims are unclear. It is unclear what changed spatial configuration is sought after in the instant invention. Interferon is known to have divers activities such as antiviral, antiproliferative and immunomodulatory activities. It unclear

what improved efficacy is contemplated in claim 1 (see also rejection 6a). Claims 2-9, 11 and 23-24 are rejected insofar as they are dependent on rejected claim 1.

7c. Claim 3 is rejected as being vague and indefinite because US Patent Nos. 4, 695, 623 and 4, 897, 471 describe multiple interferon proteins. Thus, it is unclear higher efficacy in which function(s) is (are) contemplated. In addition, it is also unclear which interferon is compared to.

7d. In claim 4, Applicants contemplate unique secondary or tertiary structure of the super-compound interferon. However, it is unclear what unique secondary or tertiary structures are contemplated.

7e. Claim 5 is rejected as being vague and indefinite because there is no teaching to correlate the 3-dimensional change and the production process.

7f. Claim 23 is rejected as being vague and indefinite because it is unclear what the suitable carrier is intended to do.

Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8a. Claims 1-6, 9, 11 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Day et al. (1992).

Day et al. describes recombinant murine interferon-β, which has increased specific activity (15 fold). It also describes increased antiviral activity (see abstract).

Further, the reference teaches that residues at 17, 29 and 136 have been changed which would change the spatial configuration of the polypeptide. Although, not described by Day et al., the presence of Cys residues at positions at 29 and 136 will change the secondary or tertiary structure by the formation of disulfide bond. This will also result in the change in the 3-dimensional change of the protein (see page 142, 2nd column). Thus, meeting the limitation(s) of claims 1-5 and 9. In addition, the reference teaches the expression of interferon in E.coli under the control of λ phage P_L promoter meeting the limitation of claim 6 (page 141). Although, not disclosed by Day et al. the recombinant interferon will inherently contain the ability to inhibit DNA duplication and secretion of HBsAg and HBeAg of Hepatitis B Virus because of the increased antiviral activity. Thus, meeting the limitation of claim 11. Day et al. also describe recombinant interferon in suitable carrier (page 141), meeting the limitation of claim 23.Therefore, claims 1-6, 9, 11 and 23 are rejected as being anticipated by Day et al. (1992).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9a. Claims 7, 8 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al. in view of Olsen et al (U.S. Patent No. 6, 114, 145) and Nasoff et al. (1999).

The teachings of Day et al. have been described above in paragraph 8a. However, the Day et al. reference does not teach interferon cDNA with codons adjusted for expression in E. coli and expression under the control of pBAD promoter. It also does not teach the suitable carrier and pharmaceutical compositions with interferon.

Olsen et al. have described Synferon a novel protein that relates to interferon family (abstract). It also teaches methods to optimize expression in hosts such as E.coli by modifying the codon usage(column 6, lines 43-47). It also teaches interferons in pharmaceutically acceptable carrier (column 21).

Nasoff report in Expression (April 1999), that pBAD promoters which are capable of expressing high levels of the protein of the human genes in E.coli. pBAD promoters are tightly regulated by inducer arabinose (see pages 10 and 11 included). Therefore, it would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to generate the recombinant murine interferon-β described by Day et al. to include E. coli specific codons and express the protein under E.coli pBAD promoter reported by Olsen et al and Nasoff et al. The person of ordinary skill in the art

would have been motivated to modify the interferon codons to that of bacterial host to optimize the expression as described by Olsen et al. and also under the control of pBAD promoter because this will allow one of skilled in the art to efficiently express the recombinant interferons in E.coli. There is a reasonable expectation of success because Day et al. and Olsen et al. have both expressed the mammalian interferon protein in E.coli. Furthermore, the recombinant interferon expressed in E.coli can also formulated in pharmaceutically acceptable carrier as described in Olsen et al. Therefore, the claims 7, 8 and 24 are obvious over Day et al. in view of Olsen et al (U.S. Patent No. 6, 114, 145) and Nasoff et al. (1999).

10. No Claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 08/05

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER